

Serial No. 09/777,091

PATENT

IN THE CLAIMS:

Please cancel claims 7-9, 14, 17-36, and 46-54 without prejudice and amend the claims as follows:

- 1 1. (Amended) An implantable valve for a bodily passage of tubular shape,
- 2 comprising:
- 3 a self-expanding support frame configured for expansion to conform
- 4 to a wall of the bodily passage, said support frame having a plurality of
- 5 bends, said plurality of bends configured to provide outward radial force
- 6 for expansion of said self-expanding frame to anchor the implantable valve
- 7 to the wall of the bodily passage, said support frame when expanded
- 8 providing a plurality of side elements each defining a path extending at
- 9 least partially longitudinally along the wall and at least partially
- 10 circumferentially around the wall,
- 11 a plurality of leaflets, each leaflet thereof having a body extending
- 12 from a wall-engaging outer edge to an inner edge proximate a
- 13 corresponding inner edge of at least one other leaflet of the plurality of
- 14 leaflets,
- 15 the inner edges of said plurality of leaflets cooperable to define an
- 16 opening therebetween to permit fluid flow in a first direction along the
- 17 bodily passage, and further cooperable to engage each other sufficiently to
- 18 restrict fluid flow in a second direction opposing the first direction,
- 19 the outer edge of each one of the plurality of leaflets attached along
- 20 one side element of said plurality of side elements and thereby adapted to
- 21 sealingly engage the wall of the bodily passage in said path extending at
- 22 least partially longitudinally and at least partially circumferentially such
- 23 that the leaflet extends along said bodily passage away from the inner
- 24 edges in said second direction, each of said leaflets thereby forming a
- 25 curved structure for trapping fluid between the leaflets and the inner wall
- 26 of the bodily passage in response to fluid flow in said second direction so

Serial No. 09/777,091

PATENT

27 as to cause said inner edges of said leaflets to engage one another  
28 sufficiently to restrict fluid flow in said second direction.

1 2. (Amended) The implantable valve of claim 1, wherein at least a portion  
2 of the body of the leaflet being flexible at least proximate the inner edge  
3 thereof.

1 4. (Amended) The implantable valve of claim 1 wherein the outer edges  
2 of the plurality of leaflets include overhanging material, the overhanging  
3 material extending beyond the frame to which the plurality of leaflets are  
4 attached.

1 5. (Amended) The implantable valve of claim 1 wherein said frame  
2 comprises wire to and around which the bodies of the leaflets are secured.

1 55. (Amended) An implantable valve for a bodily passage of tubular  
2 shape, comprising:

3 a support frame configured for expansion to conform to a wall of the  
4 bodily passage, said support frame when expanded providing a plurality  
5 of side elements each defining a path extending at least partially  
6 longitudinally along the wall and at least partially circumferentially around  
7 the wall,

8 a plurality of leaflets comprising an extracellular collagen matrix  
9 material, each leaflet thereof having a body extending from a wall-  
10 engaging outer edge to an inner edge proximate a corresponding inner  
11 edge of at least one other leaflet of the plurality of leaflets,

12 the inner edges of said plurality of leaflets cooperable to define an  
13 opening therebetween to permit fluid flow in a first direction along the  
14 bodily passage, and further cooperable to engage each other sufficiently to  
15 restrict fluid flow in a second direction opposing the first direction,

Serial No. 09/777,091

PATENT

16 the outer edge of each one of the plurality of leaflets attached along  
17 one side element of said plurality of side elements and thereby adapted to  
18 directly engage the wall of the bodily passage therearound and provide  
19 ingrowth of adjacent native tissue into the extracellular collagen matrix  
20 material.

Please add the following new claims:

1 56. (New) The implantable valve of claim 55 wherein the collagen matrix  
2 material comprises submucosal tissue.

1 57. (New) The implantable valve of claim 55 wherein the collagen matrix  
2 material comprises small intestinal submucosa.

1 58. (New) An implantable valve for a bodily passage of tubular shape,  
2 comprising:

3 a frame that includes a plurality of legs, each of the legs originating  
4 from a pair of bends located about a first end of the implantable valve, and  
5 extending in an opposite direction therefrom, each of the plurality of legs  
6 terminating at a second end of the implantable valve opposite the first end  
7 such that the plurality of legs generally assume a serpentine configuration  
8 along the circumference of a bodily passage when situated therein,

9 a plurality of leaflets, each leaflet comprising a covering that includes  
10 one or more flexible materials, the leaflet including a body that comprises  
11 a wall-engaging outer edge and an inner edge, the outer edge at least  
12 partially attached to, and reinforced by one of the plurality of legs, the outer  
13 edge and the associated leg adapted to sealingly engage the inner wall of  
14 the bodily passage,

15 wherein the body of the leaflet extends inward from the wall of the  
16 bodily passage and extending toward the first end of the implantable valve  
17 where it terminates at the inner edge, the body and inner edge traversing

Serial No. 09/777,091

PATENT

18 the lumen of the bodily passage when situated therein and being  
 19 configured such that the leaflet is cooperable with at least one other leaflet  
 20 to define an opening that permits positive flow of fluid therethrough in a  
 21 first direction, while the plurality of leaflets are further adapted to trap  
 22 between the leaflets and the inner wall of the bodily passage fluid flowing  
 23 in a second direction opposite the first direction and seal against one  
 24 another to restrict fluid flow in said second direction; and  
 25 wherein the frame is adapted to assume a plurality of configurations,  
 26 a first configuration of the plurality of configurations being a generally flat  
 27 plane.

1 59. (New) An implantable valve for a bodily passage of tubular shape,  
 2 comprising:

3 a frame that includes a plurality of legs, each of the legs originating  
 4 from a pair of bends located about a first end of the implantable valve, and  
 5 extending in an opposite direction therefrom, each of the plurality of legs  
 6 terminating at a second end of the implantable valve opposite the first end  
 7 such that the plurality of legs generally assume a serpentine configuration  
 8 along the circumference of a bodily passage when situated therein,

9 a plurality of leaflets, each leaflet comprising a covering that includes  
 10 one or more flexible materials, the leaflet including a body that comprises  
 11 a wall-engaging outer edge and an inner edge, the outer edge at least  
 12 partially attached to, and reinforced by one of the plurality of legs, the outer  
 13 edge and the associated leg adapted to sealingly engage the inner wall of  
 14 the bodily passage,

15 wherein the body of the leaflet extends inward from the wall of the  
 16 bodily passage and extending toward the first end of the implantable valve  
 17 where it terminates at the inner edge, the body and inner edge traversing  
 18 the lumen of the bodily passage when situated therein and being  
 19 configured such that the leaflet is cooperable with at least one other leaflet  
 20 to define an opening that permits positive flow of fluid therethrough in a

Serial No. 09/777,091

PATENT

21 first direction, while the plurality of leaflets are further adapted to trap  
22 between the leaflets and the inner wall of the bodily passage fluid flowing  
23 in a second direction opposite the first direction and seal against one  
24 another to restrict fluid flow in said second direction; and

25 wherein the frame is adapted to assume a plurality of configurations,  
26 a first configuration of the plurality of configurations being a generally flat  
27 plane; and

28 wherein the covering includes two leaflets such that when the frame  
29 in the generally flat configuration generally assumes a diamond shape with  
30 the inner edges of the two leaflets defining a slit therebetween.

1 60. (New) A valve prosthesis for an implantation in blood vessel,  
2 comprising:

3 a support frame including a plurality of interconnected sides, the  
4 support frame being collapsible into a first configuration for intravascular  
5 delivery into the bodily passage and expandable into a second  
6 configuration for implantation therein;

7 a plurality of leaflets, each leaflet having an inner edge and an outer  
8 edge;

1 wherein the inner edges of the plurality of leaflets are cooperable  
2 with one another to permit blood flow in a first direction within the vein,  
3 while restricting blood flow in a second direction opposite the first  
4 direction; and

5 wherein the outer edge of each of the plurality of leaflets is attached  
6 to at least one of the plurality of interconnected side elements such that the  
7 plurality of outer edges engage the walls of the bodily passage and  
8 collectively form a seal thereagainst along a pathway defined by the  
9 plurality of interconnected side elements.

1 61. (New) The valve prosthesis of claim 60 wherein plurality leaflets  
2 comprise a bioremodelable material.